

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda item 7.1

CX/RVDF 26/28/7-Add.1

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ENGLISH

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

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EXTRAPOLATION OF MAXIMUM RESIDUE LIMITS OF VETERINARY DRUGS IN FOODS TO ONE OR MORE SPECIES:

EXTRAPOLATION OF MRLs FOR CAMELIDS IN VARIOUS TISSUES -

ALBENDAZOLE, IVERMECTIN, AND OXYTETRACYCLINE

Comments at Step 3 in reply to CL 2025/11-RVDF

Submitted by:

*Argentina, Ecuador, Egypt, Indonesia, Iraq, Malaysia, Singapore,
Thailand, the United Arab Emirates (UAE), the United Kingdom, the United States of America (USA)*

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2025/11-RVDF¹ issued in January 2026. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

Explanatory notes on the Annex

2. The comments submitted through the OCS are hereby annexed and presented in tabulated format.

¹ <https://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>
<https://www.fao.org/fao-who-codexalimentarius/committees/committee/related-circular-letters/en/?committee=CCRVDF>

ANNEX**GENERAL COMMENTS**

COMMENT	MEMBER/OBSERVER
The Republic of Ecuador thanks the Secretariat of the Codex Alimentarius Commission for sharing Circular Letter CL 2026/11-RVDF and acknowledges the technical work carried out by the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF), as well as the efforts made by the Electronic Working Group (EWG), which carried out the analysis found in CX/RVDF 26/28/7. Ecuador appreciates the strict scientific standards used in evaluating the extrapolation of MRLs to camelids and the consideration given to the established technical criteria for risk assessment. Ecuador reiterates its support for decisions on extrapolation still being strictly based on strong scientific evidence, ensuring the safeguarding of public health and international regulatory consistency.	Ecuador
Indonesia has not taken a stance on the submission of data for the following CL. Indonesia considers that the extrapolation approach is acceptable, provided it is supported by adequate data and the precautionary principle to ensure consumer health protection and consistency in the implementation of international standards. However, currently, there are no camelid-derived products subject to such extrapolation in Indonesia.	Indonesia
<u>Amendment of criteria</u> Thailand believes that it is not necessary to amend the current criteria or add additional ones to facilitate the extrapolation of MRLs for specific veterinary drugs/substances to camelids. Additionally, we consider that it may not be appropriate to base extrapolation on the most conservative (lowest) MRL, as this could result in unnecessarily prolonged withdrawal periods and unintended impacts on trade and production. In cases where a veterinary drug or substance does not meet the established criteria, Thailand supports the generation of additional scientific data to address the gap. This approach would allow JECFA to carry out its risk assessment in accordance with the established risk analysis process, without the need to introduce new or revised criteria.	Thailand
The United Arab Emirates, being one of the most producers of camel milk and meat welcomes the work being undertaken by CCRVDF to extrapolate MRLs from other species to Camelids. This approach will help promoting the trade of the Camelids products internationally. The UAE agrees with the criteria proposed by CCRVDF on the extrapolation of maximum residue limits of veterinary drugs for camelids in various tissues: Albendazole, ivermectin, and oxytetracycline. The approach is considered science-based, easy to implement using the data available to CCRFDV. It is conservative enough to ensure consumer safety while allowing easier trade between members.	UAE
The United Kingdom is in support of these three recommendations.	United Kingdom

SPECIFIC COMMENTS

RECOMMENDATION 1: Extrapolating MRLs for albendazole to camelids.	MEMBER/OBSERVER
Albendazole and ivermectin We agree with the recommendation not to extrapolate albendazole or ivermectin MRLs to camelids and not to recommend an MRL for this purpose due to the lack of available traceable information on other species and certain obtained data that was evaluated. The recommended criteria in Annex C of the Codex Procedural Manual Ed 29- Oct 2024- ANNEX C (Approach for the extrapolation of maximum residue limits for veterinary drugs to one or more species) have not been met.	Argentina
Malaysia does not support the extrapolation of the MRLs established for albendazole in the edible tissue and milk of cattle and sheep to camelids, as it does not meet the criteria established by CCRVDF.	Malaysia
Ecuador agrees with the conclusion in RV28/07 that the extrapolation of albendazole MRLs to camelids is not appropriate, given that there is insufficient scientific data available to support it in accordance with the CCRVDF criteria.	Ecuador
Egypt agrees with the draft evaluations and conclusions. Egypt agrees that albendazole does not meet the extrapolation criteria set by CCRVDF, and so the existing MRLs cannot be extrapolated to camelids.	Egypt
Thailand has no objection to Recommendation 1 of EWG, which states that “the extrapolation of the MRLs established for albendazole in the edible tissues and milk of cattle and sheep to camelids is not supported”. We agree with the EWG’s rationale that the marker residue is a metabolite (2-amino-benzimidazole), not the parent compound, and that it remains unclear whether identical MRLs have been established in at least one ruminant and one non-ruminant species based on JECFA recommendations.	Thailand
Albendazole and Ivermectin Taking into consideration the described approach as per the document CX/RVDF 26/28/7, the UAE agrees that it is not possible to extrapolate MRLs for albendazole and ivermectin to camelids.	UAE
The extrapolation criteria have not been met for camelids	USA

RECOMMENDATION 2: Extrapolating MRLs for ivermectin to camelids.	MEMBER/OBSERVER
See Recommendation 1.	Argentina
Ecuador agrees with RV28/07 that it is not possible to extrapolate ivermectin MRLs to camelids, since the available data does not provide an adequate scientific basis for said extrapolation.	Ecuador
Malaysia does not support the extrapolation of the MRLs established for ivermectin in the edible tissue of cattle, sheep, goats and pigs and the milk of cattle and sheep to camelids, as it does not meet the criteria established by CCRVDF.	Malaysia
Egypt agrees with the draft evaluations and conclusions. Egypt agrees that ivermectin does not meet the extrapolation criteria set by CCRVDF, and so the existing MRLs cannot be extrapolated to camelids.	Egypt
Thailand has no objection to Recommendation 2 of EWG, which concludes that the extrapolation of the MRLs established for ivermectin in the edible tissues of cattle, sheep, goats, and pigs, and the milk of cattle and sheep, to camelids is not supported. The significant variation in established MRLs for ivermectin across reference species—for example, 800 µg/kg in cattle liver compared to 30 µg/kg in pigs—supports this position. As a result, direct extrapolation is not scientifically supported because ivermectin fails to meet the criterion of identical MRLs across species.	Thailand
See Recommendation 1.	UAE
The extrapolation criteria have not been met for camelids.	USA

RECOMMENDATION 3: Extrapolating MRLs for oxytetracycline to camelids.	MEMBER/OBSERVER
Recommendation 3.1: Oxytetracycline Argentina supports the extrapolation of oxytetracycline to camelid tissues and milk, in accordance with the criteria established by CCRVDF. Recommendation 3.2: Tetracycline and chlortetracycline Additionally, it is appropriate for CCRVDF to consider tetracycline and chlortetracycline, which are substances used in national veterinary practice, in this working group for evaluation.	Argentina
Recommendations 3.1 and 3.2: Oxytetracycline, tetracycline, and chlortetracycline Oxytetracycline: Ecuador agrees with the conclusion in RV28/07 highlighting that it is possible to extrapolate oxytetracycline MRLs to camelids, given that there is enough scientific data supporting this decision, including the technical considerations relating to the MRL calculation established for tetracyclines.	Ecuador
Recommendation 3.1: Oxytetracycline Egypt agrees that oxytetracycline meets all criteria set by CCRVDF for MRL extrapolation to camelids edible tissues and milk. Egypt agrees with the draft recommendation to extrapolate the oxytetracycline MRLs for cattle, sheep, pigs, and poultry to camelid species. Recommendation 3.2: Tetracycline and chlortetracycline Since the same criteria are also met for both tetracycline and chlortetracycline (and the marker residue is the sum of all three compounds), it is additionally recommended that the MRLs established for tetracycline and chlortetracycline are extrapolated to camelids (edible tissues and milk).	Egypt
Yes	Iraq
Malaysia supports the MRLs established for oxytetracycline in the edible tissues of cattle, sheep, pigs, and poultry, and the milk of cattle and sheep can be extrapolated to camelids.	Malaysia
Recommendation 3.1: Oxytetracycline Singapore is supportive of having new codex MRLs for oxytetracycline in camelid tissues and milk through extrapolation. The extrapolation has fulfilled the criteria and the extrapolated MRLs have incorporated sufficient safety margin to protect consumers.	Singapore
Recommendation 3.1: Oxytetracycline Thailand supports extrapolating the MRLs established for oxytetracycline in the edible tissues of cattle, sheep, pigs, and poultry, and the milk of cattle and sheep, to camelids. Recommendation 3.2: Tetracycline and chlortetracycline Thailand is unable to support Recommendation 3.2, as it is not consistent with the CCRVDF work process. Thailand believes that any consideration of veterinary drugs for MRL extrapolation must strictly adhere to the standard working procedures of CCRVDF, even though these substances have the same ADI and marker residue as oxytetracycline. Before official consideration of extrapolation can begin, tetracycline and chlortetracycline should be proposed for inclusion in the Priority List, and the work must be approved by CAC.	Thailand

RECOMMENDATION 3: Extrapolating MRLs for oxytetracycline to camelids.	MEMBER/OBSERVER
Recommendation 3.1: Oxytetracycline The extrapolation is only possible and agreed on for Oxytetracycline. Recommendation 3.2: Tetracycline and chlortetracycline The UAE recommends that the extrapolation be extended also to Chlortetracycline and tetracycline, although these metabolites are not included in Part V of the priority list. Having extrapolated MRL for all tetracyclines will improve trade between countries and help ensure consumer safety. Conducting controlled residue studies in camelids would provide the scientific basis required for JECFA to establish safe and appropriate MRLs for these species, which are of growing economic and food security importance in the MENA region. This approach would address the data gaps identified in Appendix I and support future risk-based decision-making.	UAE
Recommendation 3.1: Oxytetracycline The extrapolation criteria have been met. The MRLs in cattle, sheep, pigs, and poultry can be extrapolated to camelid species, including the MRLs for milk. Recommendation 3.2: Tetracycline and chlortetracycline Upon agreement among the Committee that proper procedure has been followed, the United States would also support the proposal to extrapolate the MRLs for tetracycline and chlortetracycline.	USA